

Elaine Hughes
4870 Mac Arthur Boulevard, NW, #6, Washington, DC 20007
202-333-0537 ehughes@nfcvp.org

March 20, 1999

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

5902 '99 MAR 24 16:47
RE: **FDA Docket No. 98N-1265**

Dear FDA:

I am writing in regard to the above-referenced Memorandum of Understanding (MOU) that you have been circulating to state boards of pharmacy throughout the country.

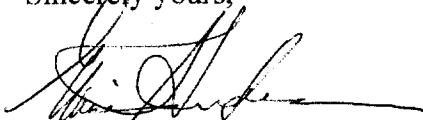
I want you to know how strongly I oppose this MOU. I have been using compounded medication since 1993 - approximately one year after a hysterectomy and oophorectomy. The difference that the compounded medication has made in my life has been dramatic. Prior to using the compounded meds, I was on Premarin and had debilitating symptoms, such as depression, seriously depleted energy levels, and sleeplessness. If you pursue putting the MOU into practice, you will be preventing me and countless others from obtaining the very medications -- prescribed by our doctors -- that have improved our health remarkably and have made it possible for us to function in a normal way.

While on Premarin, I suffered being unable to resume any normalcy in my life. I researched menopause extensively and learned that one of the best gynecologists around was right here in Washington (at Georgetown University Hospital at the time) - Dr. James Simon. When he put me on the compounded medications, all the symptoms that were impeding my functioning stopped. I had had severe hip pain as a result of the loss of bone mass -- I was diagnosed as osteopoenic (pre-osteoporosis). **With compounded medications, the hip pain disappeared, there have been no adverse side effects, and, unexpectedly, the deterioration of my bones has been stopped and slightly reversed! I have the bone scans to prove it!**

There is no comparison between what my life was like before the compounded meds and what it is like now. Please, please, please, pay attention to the needs of the citizens of this country. It would be a grave injustice to force us to accept only drugs made by large pharmaceutical companies!! I expect the FDA to be smart and neutral when it comes to the lobbying of these pharmaceutical companies. Do not betray the citizens to whom you are responsible and to whom choice in health care and medications is critical.

Thank you for considering my views.

Sincerely yours,


Elaine Hughes

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Dockets Management Branch (HFA-305)
Docket No. 98N-1265
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I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Signature

Date

COMMENTS:

See enclosed letter.

Please fold, seal, and mail by March 22

Hughes
4870 MacArthur Blvd NW #6
WDC 20007



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